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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art. Unit: 3626 }
Atty. Docket: 9110-0008 }
Applicant: Meek et al. }
Title: HEALTHCARE }
MANAGEMENT }
SYSTEM AND }
METHOD OF }
PREDICTING HIGH }
UTILIZERS OF }
HEALTHCARE }
SERVICES }
Serial No.: 09/520,419 }
Filed: March 8, 2000 }
Examiner: Bleck, C. }

Certificate Under 37 C.F.R. § 1.8(a)

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on January 12, 2004

D. Cwiklinski

Dated: January 12, 2004

APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is submitted in response to the Notification of Non-Compliance mailed December 22, 2003. A Final Rejection was issued February 4, 2003. Pursuant to 37 C.F.R. § 1.192, an Appendix containing a copy of the claims involved in the appeal is attached. The claims in the Appendix reflect amendments submitted herewith in a separate paper designed to simplify issues for appeal. Please charge any additional fees due, or credit any overpayment, to Bose McKinney & Evans LLP's Deposit Account No. 02-03223.

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Real Party in Interest

The above-referenced application has been assigned to The Haelan Corporation, which is an Indiana corporation headquartered in Indianapolis, Indiana.

Related Appeals and Interferences

There are no related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Pending entrance of the amendment filed herewith on a separate paper, claims 1-4, 6-10, and 22 are pending in the above-identified application and are attached hereto as Appendix A.

Claims 1, 8-10, and 22 are rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,976,082 to Wong et al. ("Wong").

Claims 2-3 are rejected under 35 USC §103(a) as being unpatentable over Wong in view of U.S. Patent No. 5,486,999 to Mebane ("Mebane").

Claim 4 is rejected under 35 USC §103(a) as being unpatentable over Wong in view of U.S. Patent No. 6,269,339 to Silver ("Silver").

Claim 7 is rejected under 35 USC §103(a) as being unpatentable over Wong .

In the Advisory Action, the Examiner treated claim 6 as cancelled. No rejection and no indication of allowable subject matter was issued for claim 6. However, claim 6 was not cancelled by the Applicant.

Accordingly, claims 1-4, 6-10, and 22 are on appeal.

Status of Amendments

Five amendments subsequent to the Final Rejection were filed on April 17, 2003, May 14, 2003, June 25, 2003, August 1, 2003, and September 9, 2003. Each amendment except the September 9, 2003 was denied entry prior to this Appeal. Another amendment is filed herewith in a separate paper. The amendments of the separate paper are reflected in the claims displayed in Appendix A.

Summary of the Invention

The following is a concise explanation of the invention defined in the claims involved in this appeal. However, the citations in the following summary should not be construed as

the only locations of support in the application for the claims involved in this appeal. Further, the following should not be construed to limit the claims involved in this appeal or any other patentable feature of the present disclosure.

With regard to amended independent claim 1 as shown in Appendix B, the present invention includes a method of managing healthcare services as shown in Fig. 3, comprising the steps of: collecting information from an individual for a predetermined set of predictive factors (310); assigning, based upon said information from said individual, a separate value to each predictive factor of said predetermined set of predictive factors (330); generating, based upon a predetermined predictive model and said separate values assigned to said predetermined set of predictive factors, a risk level of said individual utilizing healthcare services at a predetermined level within a prospective time span (340,350); wherein said assigning step comprises the steps of: determining, based upon said information, whether a first predictive factor is indicative of a high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span; assigning, based upon said information, a first dichotomous value to said separate value for said first predictive factor if said determining step determines that said first predictive factor is indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span; and assigning, based upon said information, a second dichotomous value to said separate value for said first predictive factor if said determining step determines that said first predictive factor is not indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span. (Applicants' specification, page 8, line 3- page 10, line 16).

Issues

- I. Is amended claim 1 unpatentable over Wong under 35 USC §102(b)?
- II. Does claim 22 add new matter to the present application as originally filed?

Grouping of Claims

Claims 1-4, 6-10, and 22 are believed to be separately patentable. However, for the purposes of this appeal, the claims are grouped as follows.

Group I: Claims 1-4, 6-10, and 22

Arguments

I. Claim 1 is patentable over Wong under 35 USC §102(b).

All of the claims on appeal depend from claim 1. Claim 1 has been amended to include the limitations of original claim 5, which also depended from claim 1, to place the application in better form for appeal. The rejection of claim 1 is a rejection under 35 U.S.C. §102(b) based on Wong. Without admitting anything regarding the merits of the other rejections of the dependent claims on appeal, and in order to simplify the issues presented in this appeal, Applicants only argue herein that the rejection of claim 1 is improper. If claim 1 is found allowable over Wong, then all of the claims on appeal should be allowed.

Wong discloses a method for identifying at risk patients diagnosed with congestive heart failure. Wong teaches a computer-implemented technique, including database processing, to identify at risk congestive heart failure patients where information about the patients exists in a claims database. Wong samples only patients who are known to 'already have had congestive heart failure. (Title, Abstract).

The Wong system utilizes a plurality of independent variables representing potential predictors of adverse health outcomes to predict outcomes which are represented in Wong as dependent variables. (Col. 12, lines 28-31). Wong scans the claims database and extracts information for independent variables such as Age, Gender, HMO membership, site code of first CHF diagnosis, presence of Ischemic Heart disease, Number of ACE inhibitor prescriptions, and many others. (see Table 1, col. 12-13). These values, which are indicative only of medical information values recorded in claims, are put into an algorithm.

The algorithm outputs values for dependent variables which represent events such as hospitalization for CHF, high cost, and death. These dependent variable outcomes can be represented by dichotomous values indicating the event either happening/existing or not happening/existing. (Col. 13, lines 19-47).

Claim 1 requires, among other things, the step of

“assigning, based upon said information [from an individual for predictive factors], a separate value to each predictive factor of said predetermined set of predictive factors; ... wherein said assigning step comprises the steps of: determining, based upon said information, whether a first predictive factor is indicative of a high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span; assigning, based upon said information, a first dichotomous value to said separate value for said first predictive factor if said determining step determines that said first predictive factor is indicative of said high risk of said individual utilizing said

healthcare services at said predetermined level within said prospective time span; and assigning, based upon said information, a second dichotomous value to said separate value for said first predictive factor if said determining step determines that said first predictive factor is not indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span.”

In other words, the assigning step of claim 1 requires assigning a separate value to each predictive factor by (1) determining whether the factor indicates a high risk, and (2) assigning a first dichotomous value to the separate value of the factor if the factor indicates a high risk, or (3) assigning a second dichotomous value to the separate value of the factor if the factor does not indicate a high risk.

Wong fails to teach the step of determining whether a certain predictive factor is itself indicative of a risk. Wong takes many factors as shown by independent variables and inserts them into an algorithm without any analysis as to whether any one of the independent variables itself is indicative of a risk. The analysis of Wong determines whether a group of independent variables as a whole is indicative of any of the dependent variables. It is then these dependent variables, the output of the algorithm, that are expressed as dichotomous values.

The Examiner rejected claim 1 in the Official Action of October 9, 2003 stating:

“As per claim 1, Wong discloses... (d) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);”

As a preliminary matter, Applicants respectfully submit that the disclosed step in Wong of determining that a first predictor is correlated or in some way relates to a patient's healthcare use does not constitute disclosure of determining whether a factor indicates a high risk of healthcare use. The Examiner is arguing that Wong determines whether a factor relates to healthcare use. Claim 1, on the other hand, requires a determination of how a factor relates to healthcare use before using the factor as an input to the predictive model. Claim 1 states that the set of predictive factors is predetermined. (See collecting step). The claimed method assumes these factors relate to healthcare use. Any analysis to determine whether such factors relate to the output has already been performed. The assigning step of claim 1

further requires a determination of how the factors relate to healthcare use. (i.e., high risk or not). This analysis is performed prior to entering data into the predictive model that generates the overall risk level of healthcare use. This analysis is not analogous to determining if the predictive factor is correlated. Knowing that something is correlated and knowing what it indicates are not the same thing.

The Examiner continued with her rejection in the Official Action of October 9, 2003 stating,

“As per claim 1, Wong discloses...

(e) assigning, based upon information, a first dichotomous value, such as “1”, to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(f) assigning, based upon information, a second dichotomous value, such as “0” to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using healthcare resources at a predetermined level, such as cost over a predetermined timer interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54.)”

Although some of the many cited passages to Wong relate generally to variables used in predictive modeling, it is entirely unclear to the Applicant, after careful review of these passages, where the Examiner finds specific support for her rejection. Wong describes a prediction system involving independent and dependent variables. Wong describes the difference between the two variables as follows:

“The dependent variables are representative of the desired result (i.e., an adverse health outcome to be predicted); whereas, the independent variables are representative of predictors.” (col. 5, lines 5-8).

Thus, the independent variables of Wong are the predictors input to the algorithm and the dependent variables of Wong are the predicted values that the algorithm outputs. The Examiner stated that Wong teaches “using independent variable representing potential predictors of adverse health outcomes, wherein the independent variables of interest including assigning a yes or no (Y/N) to the following variables: ischemic heart disease, diabetes, adverse lifestyle diagnosis, cardiac dysrhythmias, other heart disease, and hypertensive disease.”

However, claim 1 requires that the value of the dichotomous value be itself indicative of a likelihood of either high or low risk. In the present invention, if a “1” is input for the criteria of “Absent from work in the last six months,” then the user knows that the patient’s history of work attendance indicates that the patient is likely to have near term healthcare use. Once all variables used by the algorithm are considered, the overall assessment may be that the patient is not likely to have near term healthcare use, but the specific predictor of “absent from work in the last six months” indicates that the patient is likely to have near term healthcare use.

The values input into the algorithm (independent variables) of Wong, on the other hand, are simply data values. The data values themselves do not indicate the likelihood of healthcare use. Table 1 of Wong (col. 12-13) states various independent variables. If a patient answers that he has had 2 other CV prescriptions (variable #15), the value of 2 that is input into the algorithm does not indicate near term use. The value of 2 for “other CV prescriptions” could be normal, or it could be catastrophically abnormal. Likewise, a value of Y for ischemic heart disease (one of the variables cited by the Examiner) only indicates that ischemic heart disease has been present in the past. This value does not itself indicate whether the answer is high or low risk. The input values (independent variables) of Wong have not gone through a determining step or an assigning step previous to being put into an algorithm to effect a generating step as required by claim 1. Wong fails to assign a first or second dichotomous value to a predictive factor indicating that the information collected for that predictive factor is itself indicative of high or low risk. In that Wong does not teach analyzing whether a predictive factor itself indicates a high risk, Wong certainly can not teach assigning one of two dichotomous values to the predictive factor based upon the outcome of such an analysis.

Even the Examiner appeared to recognize the differences between Wong and the subject matter of amended claim 1. During a telephonic interview on April 9, 2003, the Examiner indicated that Wong did not appear to teach the limitations of previously pending claim 5, which have now been included in claim 1.

In summary, Wong fails to teach evaluating data before entering it into an algorithm. Wong fails to teach that dichotomous input values are themselves indicative of a high or low risk of the individual utilizing healthcare services. For at least these reasons, Applicants submit that independent claim 1, and claims 2-4, 6-10 and 22 that depend therefrom, patentably define the invention over Wong. Applicants respectfully request reversal of the Examiner's rejections.

II. The addition of claim 22 did not add new matter.

Claim 22 was added by the first official action response. The Examiner asserted that claim 22 was not supported by the specification as originally filed. Therefore, Applicants pointed out support in the specification for each of the new claims in the next filed response. The Examiner did not restate the new matter rejection in the Advisory Action, but also did not explicitly remove the new matter rejection. Therefore, Applicants note that with respect to claim 22, the Examiner was directed to page 11, lines 11-12 of the specification.

Claim 22 reads:

22. The method of claim 1, further comprising the step of:
defining a first reference date in the future; wherein the generating step includes generating said separate values assigned to said predetermined set of predictive factors, a risk level of said individual utilizing healthcare services at a predetermined level in the time period between a present date and the first reference date.

Page 11, lines 11-12 read:

“ ‘Total encounters’ over the subsequent six-month period was chosen as the dependent variable.”

Thus, while claim 1 generally recites prediction in the future, claim 22 recites a set period of time in the future on which to focus. Page 11, lines 11-12 specifically state that an embodiment was envisioned where a finite time period is used. Accordingly, Applicants respectfully submit that claim 22 does not add new matter, and the Examiner's rejection should be reversed.

Conclusion

In view of the above, Applicants request that the present rejections be reversed and a Notice of Allowance be issued in due course.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ryan C. Barker", written over a horizontal line.

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APPENDIX A
APPLICATION SERIAL NO. 09/520,419
APPEAL BRIEF

CLAIMS AS PENDING BASED ON LAST AMENDMENT

1. (Previously Presented) A method of managing healthcare services, comprising the steps of:

collecting information from an individual for a predetermined set of predictive factors;

assigning, based upon said information from said individual, a separate value to each predictive factor of said predetermined set of predictive factors;

generating, based upon a predetermined predictive model and said separate values assigned to said predetermined set of predictive factors, a risk level of said individual utilizing healthcare services at a predetermined level within a prospective time span;

wherein said assigning step comprises the steps of:

determining, based upon said information, whether a first predictive factor is indicative of a high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span;

assigning, based upon said information, a first dichotomous value to said separate value for said first predictive factor if said determining step determines that said first predictive factor is indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span; and

assigning, based upon said information, a second dichotomous value to said separate value for said first predictive factor if said determining step determines that said first predictive factor is not indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span.

2. (Original) The method of claim 1, wherein said collecting step comprises the step of:

presenting said individual with a self assessment questionnaire designed to elicit said information from said individual for said predetermined set of predictive factors.

3. (Original) The method of claim 1, wherein said collecting step comprises the step of:

presenting said individual with a questionnaire designed to elicit said information from said individual for said predetermined set of predictive factors, said predetermined set of predictive factors consisting of past healthcare use factors, demographic factors, perceived health factors, disease factors, healthcare compliance factors, healthcare belief factors, healthcare preference factors.

4. (Original) The method of claim 1, wherein said collecting step comprises the step of:

presenting, to a web browser, a questionnaire that elicits said information from said individual for said predetermined set of predictive factors;
receiving, via said web browser, said information for said predetermined set of predictive factors in response to said presenting step.

5. (Canceled).

6. (Original) The method of claim 1, wherein said assigning step comprises the steps of:

determining, based upon said information, whether each predictive factor of said set of predictive factors is indicative of a high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span;

assigning, based upon said information, a separate first dichotomous value to

each said separate value of each predictive factor of said set of predictive factors that said determining step determines is indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span; and

assigning, based upon said information, a separate second dichotomous value to each said separate value of each predictive factor of said set of predictive factors that said determining step determines is not indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span.

7. (Original) The method of claim 1, wherein said assigning step comprises the steps of:

determining, based upon said information, whether each predictive factor of said set of predictive factors is indicative of a high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span;

assigning, based upon said information, a “1” to each said separate value for each predictive factor of said set of predictive factors that said determining step determines is indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span; and

assigning, based upon said information, a “0” to each said separate value for each predictive factor of said set of predictive factors that said determining step determines is not indicative of said high risk of said individual utilizing said healthcare services at said predetermined level within said prospective time span.

8. (Original) The method of claim 1, further comprising the steps of:

determining, based upon said risk level for said individual, whether a high risk exists that said individual utilizing said healthcare services at said predetermined level within said prospective time span;

determining, based upon said information from said individual, at least one intervention program for said individual in response to said determining step determining that said high risk exists that said individual utilizing said healthcare services at said predetermined level within said prospective time span.

9. (Original) The method of claim 1, wherein said generating step comprises the step of:

generating, based upon said separate values assigned to said set of predictive factors and a logistic regression formula of said predictive model, said risk level of said individual utilizing said healthcare services at said predetermined level within said prospective time span.

10. (Original) The method of claim 1, wherein said generating step comprises the step of:

generating, based upon said separate values assigned to said set of predictive factors and a logistic regression formula of said predictive model, a probability value indicative of said risk level of said individual utilizing said healthcare services at said predetermined level within said prospective time span; and

determining, based upon said probability value and a predetermined threshold, said risk level of said individual utilizing said healthcare services at said predetermined level within said prospective time span.

Claims 11-21 (Canceled)

22. (Previously presented) The method of claim 1, further comprising the step of:

defining a first reference date in the future; wherein the generating step includes generating said separate values assigned to said predetermined set of predictive

factors, a risk level of said individual utilizing healthcare services at a predetermined level in the time period between a present date and the first reference date.

Claims 23-27 (Canceled)

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